Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for bacillus clausii multi-antibioresistant spores, the scientific conclusions are as follows:

Based on the review of post-marketing data, the PRAC considered that a causal association between the administration of Bacillus clausii and bacteraemia is plausible. As clinicians need to be aware of this risk, especially if the medicinal product is administered to immunocompromised patients, the PRAC considered that section 4.8 of the Summary of Product Characteristics (SmPC) should be updated to reflect this adverse drug reaction with a frequency of 'not known'. The package leaflet is updated accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for bacillus clausii multi-antibioresistant spores the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing bacillus clausii multi-antibioresistant spores is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing bacillus clausii multi-antibioresistant spores are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction(s) should be added under the SOC Infections and infestations with a frequency not known:

bacteraemia (in immunocompromised patients)

Package Leaflet

- Section 4

Unknown frequencies side effects (may affect less than 1 in 10,000 people):

In case of reduced body's defence mechanisms and you are taking <product name>, Bacillus clausii may be found in your blood.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position :	28 October 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 December 2017